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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,622	03/30/2005	John D. Cleary	11636N/020724	1994

32885 7590 11/28/2007  
STITES & HARBISON PLLC  
401 COMMERCE STREET  
SUITE 800  
NASHVILLE, TN 37219

EXAMINER
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PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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11/28/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/529,622

Applicant(s)

CLEARY ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007 and 09 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2007 has been entered.

Claims 1-8, 17, 18 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "4% or less of impurity products" (claim 1) and "impurities comprise at least one of non-amphotericin B polyene compound or an endotoxin compound" (claims 17, 18 and 21) is not disclosed in the specification as originally filed. Note that the terminology "4% or less" encompasses 0% for which there is no support in the specification as originally filed.

Applicant's arguments filed October 23, 2007 have been fully considered but they are not persuasive.

Applicant contends that both the terminology "greater than 96% pure" and the terminology "4% or less impurity products" can be readable on 100% purity. This argument has not been found persuasive. On page 3, lines 14-16 of the specification, it is stated that "the amphotericin B formulation comprises no greater than about 4% by weight of impurities". From, that terminology, it is not clear whether applicant can

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produce a product that is 100% pure. The only purification example 6 set forth in the specification produces a product that is 98% pure. Thus, there is no support in the specification, as originally filed, for a product that is 100% pure. Further, applicant has not pointed out where in the specification support can be found for the description of impurities and has not presented evidence that such impurities can consist only in non-amphotericin B polyene compounds and endotoxin compounds.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Berenstein et al (U.S. Patent No. 4,663,167) in view of Michel et al (U.S. Patent No. 4,902,789) or Tang (U.S. Patent No. 4,308,375).

Lopez-Berestein et al disclose a method of treating fungal infections with a composition comprising amphotericin B but do not disclose purification of amphotericin B. However, since purification of amphotericin B was well known in the art at the time the claimed invention was made as disclosed by Michel et al or Tang, a person having ordinary skill in the art at the time the present invention was made to use purified amphotericin B in the composition and method disclosed by Lopez-Berestein et al because such a person would have expected less side effects with administration of purified amphotericin B.

Applicant's arguments filed October 23, 2007 and November 9, 2007 have been fully considered but they are not persuasive.

Applicant contends that the purification methods disclosed in U.S. Patents "789 and '375 would not result in a product having claimed purity.

Applicant contends that the primary reference fails to disclose the claimed purity. This argument has not been found persuasive. The declaration filed states that the product achieved by the method of example 6 has an apparent purity of 98% and that the product of recrystallization method 1 disclosed by the art of record result in an apparent product having 95%. However, note that claims 1, 4-6, 17-18, 22 and 24 read on a product that is 94% pure or 95% pure. Thus, a product encompassed by said claims has the same purity level as a product that can be produced by the prior art process. Claims 2, 7, 18-21 and 24 read on a product that is greater than about 96% pure. Claims 3 and 8 read on a product that is greater than 98% pure. The difference in purity levels of 95% and 96% percent is not seen to be significant and further can be

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attributed to minor variations in the method of purification used or to An experimental error. Further, the term "about" means that the compounds encompassed by the present claims are not limited to the purity of 96% or 98% but also encompass compounds having purity levels of less than 86% or 98% levels, such as purity levels of the prior art compounds or the purity of compounds which can be achieved by the known purification methods. Also note that it is not clear from data set forth in the declaration, what specific recrystallization methods were utilized.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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